IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' REPLY BRIEF TO DEFENDANTS' BRIEF IN OPPOSITION OF PLAINTIFFS' MOTION TO EXPAND THE SCOPE OF DISCOVERY

Plaintiffs' Cross-Motion demonstrates the relevance of the manufacturing processes at Defendants' facility in Little Falls, because the facts show a close relationship exists in the manufacturing processes of the plant as a whole and Digitek®. Contrary to Defendants' assertions, at this state in the litigation, relevancy is not determined under the Federal Rules of Evidence. During the discovery phase, relevance is determined under the Federal Rules of Civil Procedure, and given the insight into the plant processes already discovered to date, Plaintiffs clearly are entitled to relief. Plaintiffs will show:

1. **Plaintiffs are entitled to discovery regarding all products produced at the Little Falls plant because a reasonable relationship exists between the manufacturing practices of Digitek® and the rest of the product lines.**

2. **The discovery and testimony to date supports a finding that the manufacturing processes are in fact reasonably related.**

3. **Defendants' claim that Digitek® was recalled due to "Double Thick" tablets is merely a red herring.**

4. **Expanding discovery of relevant information is proper based on the Federal Rules pertaining to discovery, controlling legal principles, and a favorable cost benefit analysis of the documents sought.**

5. **The information requested is relevant under the Federal Rules of Civil Procedure and broadening the scope of discovery is proper because well reasoned case law supports such action.**

6. **Broadening the scope of discovery would in fact lead to a cost saving approach, and would not be unduly burdensome.**

Defendants are in error in their claim that this litigation is limited solely to the Digitek® manufacturing process. This litigation stems from the inability of the Actavis Quality Systems (QS) (both quality control and quality assurance) to perform their function with regard to the Current Good Manufacturing Procedures (cGMP) for all of the pharmaceuticals manufactured at the Actavis Totowa Plant. The many cGMP violations received by Defendants are clearly systemic and apply to many if not all products manufactured at this plant. This warrants an expansion of scope of discovery to systemic QS violation and supporting documents to the same.

As a result of the FDA investigations conducted in 2006 through 2008, it became apparent to both the FDA and Defendants that the short falls within the QS department of Actavis required the suspension of all products manufactured in that time frame. A central allegation in this case is the inadequate QS that allowed improperly manufactured tablets to go undetected. Thus, Defendants' argument that there is no apparent connection between the defects alleged and the discovery requested is in error.

Contrary to Defendants' assertions, the repeated pattern of poor manufacturing practices and inept quality assurance and control at the Little Falls plant is relevant to this litigation. Defendants raise strawmen arguments that allowing discovery of demonstrative relevant facts will be burdensome. The facts brought before this Court this court prove that additional lines of inquiry are not simply allowed by the rules but are essential to a proper understanding of the systematic problems of the Totowa plant.

While the April, 2008 recall focused on "double-thick" pills, the Master Complaint alleges that "the amount of active ingredient was not consistent among Digitek® (Digoxin)

tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label." (ECF No. 73 ¶ 78.) Plaintiffs have consistently maintained that the "Double-Thick" pill is not the focus of the litigation. This position is backed up by the warning letters that are cited in the Master Complaint and the corresponding FDA 483 Inspections Forms.

ARGUMENT

I. Plaintiffs Are Entitled To Discovery Regarding All Products Produced At The Little Falls Plant Because A Reasonable Relationship Exists Between The Manufacturing Practices Of Digitek® And The Rest Of The Product Lines.

As seen in Plaintiffs initial brief, discovery up to this point, as well as the testimony produced by Defendants, a reasonable relationship exists between the manufacturing processes of Digitek® and the other Little Falls products, making the requested information relevant for purposes of discovery. Despite the straw man argument of Defendants, at no point do Plaintiffs summarily assert that all product lines are manufactured exactly the same. What has been shown is that Digitek® is manufactured on the same machines, by the same personnel and managers as the other product lines, with overlapping SOPs and training and thus manufacturing and quality problems with other lines are essential to gaining insight to the problems with Digitek®.

a. The discovery and testimony to date supports a finding that the manufacturing processes are in fact reasonably related.

As set forward in Plaintiffs' original brief, the corporate testimony from the 30(b)(6) depositions shows that the same personnel and the same machines were used in the manufacturing of Digitek® as well as the other product lines. (ECF No. 144, p. 2-4.) The statements made by the designated representatives of Defendant demonstrate that the manufacturing processes are in fact related. Additionally, the testimony of Rick Dowling, former Director of Manufacturing Operations for Actavis Totowa, bolsters the Plaintiffs' assertions. In

paragraph 23 of his affidavit, Dowling states that before equipment is re-used, it is necessary and required to disassemble and clean the machine before the next product line is started. (ECF No. 146, Exh. B). However, deficiencies in this process are precisely why Actavis received the revised FDA warning letter in 2007. The letter stated that "Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products." (ECF No. 144, Ex. F). An example given is that "Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including…Digoxin Tablets, USP, 0.25mg." *Id.* An improper cleaning validation study that was conducted in conjunction with another product but immediately before Digitek® is clearly related and relevant.

Defendants try to distinguish the manufacturing process of Digitek® from the other product lines. Their primary vehicle for this attempt is the affidavit of Richard Dowling, (ECF No. 146, Exh. B). This affidavit falls short of its intended goal by completely failing to address the cGMP testing and in house Standard Operating Procedures (SOPs) that apply to many of Actavis' products. QS is an integral part of the manufacturing process and therefore, a plant wide violation of QS a procedure affects the manufacturing process of all products. There was tremendous overlap from product to product because SOPs are department specific as testified to by Anthony Delicato the 30(b)(6) deponent for the Quality Department. The failings of the Actavis QS department ultimately resulted in the suspension of all product lines at the Actavis Totowa Plant.

Records obtained through Freedom of Information Act (FOIA) requests to the FDA contain few redactions and paint a very different picture than is alleged by Defendants. Countless examples of careless manufacturing practices and a complete lack of quality control are repeated

throughout the FDA Inspection Reports. In fact, Defendant Actavis admits to having an overburdened quality department and dangerous lack of communication between the manufacturing and quality systems in a response to an FDA observation. (Actavis' June 11, 2008 Response to FDA 483 issued to Actavis Totowa on 05/20/2008, p 15. attached as Exhibit 1.) This FDA observation stated that "written records are not always made of investigations into unexplained discrepancies and the failure of a batch of any of its components to meet specifications. Specifically, Quality Assurance investigations are not documented at the time of occurrence and are not completed in a timely manner as required" by Actavis' internal standard operating procedure. (Observation 8, FDA 483 issued to Actavis Totowa on 05/20/2008 attached as Exhibit 2.) Actavis' admission and response said,

> This observation provides examples supporting our decision that a pronounced reduction in the company's product portfolio was needed to ease the burden on our QA function and better align its resources with the demands placed on them. Our procedures require that investigations be opened, that they be completed fully and timely, that they be documented appropriately, and that appropriate actions thereafter be taken. **In too many instances, QA was burdened beyond its capacity to meet these SOP requirements.** As we have advised the [FDA] District Office, we are working to eliminate the existing backlog of investigations. Our plan is to be current by August 15, 2008. **In other Instances, QA was not notified of facts requiring an investigation. This is a behavioral situation that requires training, management support and overview, and enforcement.**

(Ex. 1, p. 15 (emphasis added)). The collapse of QS due in part to the "behavioral situation" that existed among the employees in manufacturing and the over taxed quality department, clearly illustrates the significance of the employees and the polices in the systemic problems at the plant.

Plaintiffs further find support that the product lines are related in portions of the affidavit of Richard Dowling. While the affidavit goes into tedious and irrelevant detail to state that Digitek® has its own unique packaging, ingredients and tablet press. This case does not concern the uniqueness of the product but rather the way the product is made and the practices and

procedures in place throughout the plant. Further, the affidavit significantly fails to address the commonality of Lab Testing for all products. Mr. Dowling's comments regarding Digitek® lab work are limited to paragraphs 40 and 41 of his affidavit. Paragraph 40 states that the "Laboratory testing of batch-specific Digitek® product samples occurs during the manufacture of each batch in accordance with strict product-specific protocols. The results of the laboratory testing are documented in batch-specific records." (ECF No. 146, Exh. B)

While the testing protocols for Digitek® may have been specific to that product, they were performed by the same department and personnel as other products, and they were all subject to the same systemic quality assurance violations noted by the FDA-483 inspection form, and confirmed by the suspension and recall of all products manufactured at the facility. Mr. Dowling's attempt to distinguish Digitek® as a product line that has "very little overlap between the equipment used… and the equipment used to make any of the other 106 products" is belied by his own assertion that 14 other products were blended in the same room and 10 other products used the same blender**.** (ECF No.146 at p. 35.)

Further, the FDA inspected Defendants plants on numerous occasions and each time came away with problems, most of which are "long standing problems" which Defendant has never corrected, as noted in the warning letter from August 15, 2006. (ECF No. 144, Ex.E). This first letter which Defendant summarily dismisses as only having to do with reporting violations is actually much more. The corresponding FDA 483 inspection form relating to the aforementioned letter illustrates the repeated failure to investigate and report serious adverse events related to Digitek® including a death that occurred within 2.5 hours of taking the pill. (Observation 1, FDA 483 issued to Actavis Totowa on 02/08/2006 attached as Exhibit 3.) Additionally, seventeen adverse experiences "reported by one nurse in September 2000 were not

submitted for atrial fibrillation and lack of effect when taking Digitek® (digoxin) Tablets. The nurse reported that 20 patients were switched to the innovator brand and his/her adverse experiences resolved within three weeks, only 3 reports were submitted." (Observation 4, Exhibit 3.)

Defendants also maintain that only one batch of Digitek® had out of specification pills and that none of these pills ever reached the market. This is simply not true as Defendants' own documents show otherwise. Defendants' 2004 Annual Report on Digitek® to the FDA dated 2/21/05 includes a customer complaint concerning a "Thick tablet." (Document labeled ACTAV 005697, attached as Exhibit 4.) The complaint summary says "Tablet was left in the vibrator during the set up of the machine and passed undetected." *Id.* This same instance was included in the February 2006 report to the FDA and there is no evidence that an investigation was ever conducted or training was given to operators to prevent future events. (Document labeled ACTAV006177, attached as Exhibit 5.)

Since the initial warning letters, the FDA has conducted more inspections of the Little Falls facility. The May 2008 inspection form mentions the Digitek® batch that Defendants claim led to the recall which noted that "Drug products failing to meet established specifications and quality control criteria are not rejected." (Ex. 2.) Digitek® is given as one example and the "double thick" tablets were undetected by manufacturing personnel or the quality group and were not caught until they reached packaging. The observation states that

> [a]lhough Quality Assurance was aware of the "double thick" tablet findings, the batch was then released based on AQL sampling which included visual inspection of 1330 tablets [out of a batch with 4.8 million tablets]. No additional thickness testing or analytical evaluation of the double thick tablets was conducted. No root cause was determined for the defect; however the lot was released to the market by the Quality Unit on 01/28/08 following the visual inspection. There was no documented evaluation of the approximately 89 lots that remained on the market at the time of inspection.

(Documents Labeled ACTAV028225-28226, attached as Exhibit 6.) Another FDA observation specifies numerous problems with other drugs including eleven examples of instances of the Defendants' failure to conduct a review where a product or its component failed to meet a required specification. (Ex. 2, Observation 3.) Additionally, one observation notes problems with the blend uniformity of Digitek® in manufacturing where out of specification results were obtained for three separate lots manufactured in February, March and September of 2007. Ex. 2, Observation 4; Document Labeled ACTAV028230, attached as Exhibit 7). Incredibly, "no manufacturing investigations were conducted." *Id.*

Defendants' rejection of the contents of the FDA letters and 483 investigations as relevant in suggesting a relationship between the manufacturing processes and defects there in, is absurd. These documents show that there is in fact a systemic problem in the manufacturing and quality systems at the Little Falls facility. Further, it is the uniform bad manufacturing of products that bears a reasonable relation amongst the entire panoply of products. When one considers the systemic inadequacy of the Actavis Quality Systems Department and the commonality of manufacturing equipment and procedures, Plaintiffs' requested expansion of discovery to include information concerning other products manufactured during this time period at the same facility is reasonable, and clearly calculated to lead to the discovery of relevant and admissible evidence.

b. Defendants' claim that Digitek® was recalled due to "Double Thick" tablets is merely a red herring.

The multiple cGMP violations identified above and during the FDA's 2008 inspection of the Actavis Totowa Plant, shed a harsh light on the systemic nature of Defendants' Quality Systems inadequacies. While the suspension and recall of Digitek® for the presence of "double

thick" pills was certainly a necessary step, it is by no means the sum total of the problems experienced at the plant. The violations found in the Digitek® manufacturing were but a factor in the decision to suspend the remaining sixty-three product lines for numerous cGMP violations.

While FDA observations 2, 4, 6, ,10 and 11 are specific to Digitek®, the following FDA-483 observations pertain to a number of product lines, including, but not limited to Digitek®;

> OBSERVATION 1:
> The Quality Unit routinely failed to document, investigate and address product quality issues at the time of occurrence including in-process, finished product and stability out of specification analytical results. There is no assurance that the Quality Unit has the procedures, personnel, or systems to adequately evaluate the quality or validation status to the approximately [redaction] that they can currently manufacture and release to the market…
>
> OBSERVATION 5:
> Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.
>
> OBSERVATION 9:
> Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

(Exhibit 2). There is no indication that these observations are directed solely towards any individual product line or even towards any subset of products manufactured at Actavis Totowa. These findings reveal that the Actavis Totowa QS department was unable to "adequately evaluate the quality" of **any** of their products, a situation that led to adulterated pharmaceuticals entering the stream of commerce. Adherence to the cGMP by a manufacturer ensures that adulterated or improperly manufactured medication cannot enter the medicine cabinets of those who rely on them. As shown in the discovery to date, the protections offered by Actavis QS proved too shoddy and inadequate. Thus, on April 24, 2008, based on the many observations by

the FDA, all product manufacturing and distribution was suspended at the Little Falls plant. (Letter from Sigurdur Olafsson, Deputy CEO of Actavis to Douglas Ellsworth, District Director of FDA, May 21, 2008, attached as Exhibit 8.) Information concerning Actavis' halfhearted attempts at cGMP compliance throughout their product lines at this location is clearly relevant and discoverable.

II. Expanding discovery of relevant information is proper based on the Federal Rules pertaining to discovery, controlling legal principles, and a favorable cost benefit analysis of the documents sought.

Defendants suggest that the scope of discovery should not be broadened because under the Federal Rules of Evidence the information sought would not be relevant. As previously mentioned, Rule 26 of the Federal Rules of Civil Procedure governs discovery. Defendants also rely on Judge Harris' statements at a Case Management Conference on March 27, 2009. At that same conference, Judge Harris stated "I'm not looking at one side or the other because I don't pretend to know the subtleties of the case or the details, other than the broad picture." (ECF No. 146, Ex. A). Clearly Judge Harris was not aware of the information contained in the 30(b)(6) depositions or the FDA inspection documents obtained by Plaintiffs.

a. The information requested is relevant under the Federal Rules of Civil Procedure and broadening the scope of discovery is proper because well reasoned case law supports such action.

Early pronouncements of the U.S. Supreme Court have provided the touchstone for interpreting the discovery rules and a party's obligations thereunder. "'Discovery' is one of the working tools of the legal profession.... It seems clear and long has been recognized that discovery should provide a party access to anything that is evidence in his case." *Hickman v. Taylor*, 329 U.S. 495, 515 (1947) (Jackson, J., concurring). The Supreme Court has stated that "modern instruments of discovery serve a useful purpose.... They together with pretrial

procedures make a trial less a game of blindman's bluff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent." *United States v. Procter & Gamble Co.*, 356 U.S. 677, 682 (1958). Thus, "civil trials in the federal courts no longer need be carried on in the dark. The way is now clear, consistent with recognized privileges, for the parties to obtain the fullest possible knowledge of the issues and facts before trial…" *Id.* at 501. "The discovery rules are to be accorded a broad and liberal treatment. No longer can the time-honored cry of 'fishing expedition' serve to preclude a party from inquiring into the facts underlying his opponent's case. Mutual knowledge of all the relevant facts gathered by both parties is essential to proper litigation." *Id.* at 507.

The defined scope of discovery allows parties to, "obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party. . . ." *Taggart v. Damon Motor Co.*, 2007 U.S. Dist LEXIS 3462 (ND. W. Va 2007) (quoting Fed R. Civ. P. 26(b)(1)). In discovery, evidence "need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.* (quoting Fed. R. Civ P. 26(b)(1)).

In the present case, Defendant asserts that information relating to the manufacture and quality control of other product lines is not relevant to the manufacture and quality control of Digitek®. Defendants make this claim despite the admission that Digitek® is manufactured on the same equipment as other products and that it utilizes the same employees for manufacture and quality systems for all drugs manufactured at the Little Falls facility. The evidence has already shown that Defendant was cited by the FDA for manufacturing out of specification drugs at the Little Falls facility. Without question this information that led to these out of specification results is relevant to enabling the Plaintiffs understanding of how and why Digitek® was manufactured with inconsistent amounts of the active ingredient. The evidence has also shown

that Defendant was cited by the FDA for inadequate quality assurance and control. As the quality assurance and control personnel worked on all product lines and admittedly were understaffed, quality records for the other drugs are relevant to Plaintiffs assertions of poor quality and control as it relates to Digitek®.

Defendants' cited case law supports Plaintiffs' position when all facts are taken into consideration. Defense cites *State ex rel. GMAC v. Standridge*, 181 S.W.3d 76 (Mo. 2006) to propound the standard that the subject matter of the litigation plays a key role in determining whether requested information is discoverable. The flaw in this argument however, is their attempt to limit the scope of discovery solely to the specific manufacturing process of Digitek tablets alone. In *State ex rel. GMAC*, the court held that defendant debtor's discovery request for information on **all** car sales where the company had knowledge of **any** delay of conferring title to the purchasers was overbroad, but was permissible when limited to a five year period, and including only the information regarding those individuals that the company had sued for collection when no vehicle title was transferred. Plaintiff's discovery request in the instant case is similarly limited in scope to only products manufactured at the same facility during the relevant time period.

In their review of *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212, (S.D. Ohio 1985) Defendants suggests that the Court limited discovery to information concerning drugs the Plaintiff ingested. This is not an accurate read of the case. In fact, in the original ruling, *In re Richardson-Merrell, Inc.*, 97 F.R.D. 481 (S.D. Ohio 1983) the Court found the documents to be inadmissible as they were "calculated to produce information which would portray defendant in a damaging light with regard to some of its past activities." In the instant case, the requested discovery involves documents that do not concern

only past activities, but rather systemic quality control failures concurrent to the subject matter of this litigation.

b. Broadening the scope of discovery would in fact lead to a cost saving approach, and would not be unduly burdensome.

Under the rules, facts are not discoverable if they are: (1) privileged, (2) unreasonably cumulative, (3) duplicative, or (4) fail a cost-benefits analysis. *Thompson v. Dept. of Housing and Urban Develop.*, 199 F.R.D. 168, 170 (D.Md 2001) (interpreting Fed. R. Civ P. 26(b)(1)). With a cost benefit analysis, the burden associated with discovery and the benefit presented to the party seeking discovery is balanced with: (1) the needs of the case, (2) the amount in controversy, (3) the parties' resources, (4) the importance of the issues at hand, and (5) how important said discovery will be to the resolution of the issues. *Id*.

In the present case there is a serious need for documents to be produced regarding the overall quality of manufacturing procedures at the Little Falls facility. Expansion of discovery is the only way that Plaintiffs will be able to completely understand the operations at the Little Falls facility. The documents seen to date show there was a systemic production problem at the Little Falls facility, and not an isolated problem with "double thick" pills as Defendant has suggested. Therefore, without a full insight into the workings of the plant as a whole, Plaintiffs may never be able to understand how and why the Defendant manufactured out of specification Digitek®.

Defendants have also argued that discovery should not be expanded due to the cost burden associated with reviewing documents. From the relatively small number documents produced to date, it is clear that Defendants have been painstakingly redacting otherwise relevant material. While Plaintiff does not dispute that there may be some documents, or information

contained in documents, which are arguably not directly relevant to this litigation, redacting such documents and/or information undoubtedly increases litigation time and costs for all parties involved. A review of the documents produced to date shows that the vast majority of documents contain redactions not due to privilege or trade secret, but rather because portions of the document pertain to products other than Digitek®. Thus the documents would be virtually redaction free if discovery is expanded. Allowing Defendants' to redact documents based on their version of relevance will only necessitate more motion practice and court hearings. Additionally, it makes it very hard to question a witness when all or part of a document is missing, thereby making upcoming depositions much more complicated and time consuming. The relief sought by plaintiffs will obviate the need for painstaking word by word redactions and permit the efficient production of relevant, non-privileged information.

Further, this Court's Protective Order (PTO # 12) and the Agreement Concerning Electronic Discovery (PTO # 20) serve to protect Defendant from any confidentiality breeches or inadvertent disclosures. The orders are comprehensive and should save the Defendants time and money spent reviewing documents for relevancy and privilege. Instead of taking advantage of these rulings, Defendants continue to spend hours redacting information they unilaterally consider to be irrelevant.

In regard to the Affidavit of Mr. Winchester, Plaintiffs cannot respond to the assertions without further clarification or discovery. Without billing records, contracts or other related documents, Plaintiffs cannot ascertain how much of the stated costs should be attributed to the Mylan Defendants or documents produced in various state court litigations.

In response to Mr. Winchester's claim that Plaintiffs desire to see all relevant documents will increase the cost at least threefold, for purposes of this motion, Plaintiffs are willing to limit

their requests to the documents already collected and covered by both preservation orders. In fact, during discussions concerning preservation of information, Defendants suggested that they made copies of key employees' hard-drives in the summer of 2008. As these employees' jobs are not limited to Digitek®, Defendants have likely already collected the relevant information that Plaintiffs are seeking. No further collection would be required and instead, Defendants could spend less time and money redacting and withholding documents.

The Rules of discovery encourage a broad and liberal approach that should be embraced because the information sought is relevant and passes the cost-benefit analysis test.

CONCLUSION

Defendants' brief in opposition to Plaintiffs' Motion to Expand the Scope of Discovery fails to establish that there is no connection between the Digitek® product line manufacturing and quality issues and the discovery requested. Plaintiffs have shown that the expansion of the scope of discovery to the manufacturing processes and quality records of all drugs produced at the Little Falls facility is proper. The processes have such a reasonable relation to each other that the spirit of PTO #12 is not offended, and the interest of justice is best served. For these reasons discovery should be expanded to include information relating to all manufacturing processes for all product lines produced at the Little Falls plant by the Actavis Defendants during the relevant time period.

Dated: June 26, 2009

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2009, I electronically filed the foregoing "Reply Brief To Defendants' Brief In Opposition Of Plaintiffs' Motion To Expand The Scope Of Discovery" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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